CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 20-0209V
UNPUBLISHED

TRACY SUE BEACH, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: July 11, 2022 Special Processing Unit (SPU); Dismissal; Insufficient Evidence; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Maximillian J. Muller, Muller Brazil, Dresher, LLP, PA, for Petitioner.

James Vincent Lopez, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION[1]

On February 26, 2020, Tracy Sue Beach filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury, which was caused-in-fact by the influenza ("flu") vaccine she received on October 11, 2017. Petition at 1, ¶¶ 2, 9.

However, the medical record establishes that Petitioner described two substantially different shoulder injuries and accompanying symptoms – the first immediately upon vaccination, and the second more than one-year post-vaccination.

[1] Because this unpublished Decision contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

Because she has failed to provide preponderant evidence to support or to link *either* claimed injury, I hereby DENY entitlement in this case.

I. Relevant Procedural History

Along with the Petition, Ms. Beach filed her affidavit and the medical records required under the Vaccine Act. Exhibits 1-13; Section 11(c). The case was assigned to SPU on May 22, 2020. ECF No. 9.

At the initial status conference, held on August 4, 2020, the parties discussed several issues with this case. ECF No. 12. Specifically, it appeared the medical records contained confusing evidence which did not support Petitioner's allegations, and the Petition contained several instances of incorrect medical records citations. *Id.* at 1. On September 29, 2020, Petitioner filed an affidavit from her trainer providing his recollections from October 2017 to support Petitioner's claims of onset (Exhibit 14, ECF No. 13), an amended petition with corrected medical records citations (ECF No. 14), and a status report indicating that initially Petitioner was informally treated by her sister - a registered nurse, in October 2017 (ECF No. 15).

On July 7, 2021, Respondent filed his Rule 4(c) Report opposing compensation. ECF No. 21. Respondent argued that Petitioner has not satisfied the criteria for a Table SIRVA injury or provided preponderant evidence of causation. Rule 4(c) Report at 6-7. Specifically, Petitioner's injury did not meet requirements related to onset, the location of pain and range of motion ("ROM"), and the absence of an alternative cause for a Table SIRVA claim. Rule 4(c) Report at 5-6; *see* 42 C.F.R. § 100.3(a)(XIV) & (c)(ii) - (iv) (2017) (setting forth these SIRVA requirements). Regarding Petitioner's causation-in-fact claim, Respondent noted that "[n]one of [P]etitioner's physicians causally related her complaints to her flu vaccination, and [P]etitioner has not submitted an expert report or any other evidence to establish that the flu vaccination caused her alleged SIRVA." *Id.* at 7 (citing the three-pronged test for causation set forth in *Althen v. Sec'y of Health & Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005)).

On January 18, 2022, I issued an Order to Show Cause, allowing Petitioner a final chance to obtain and to file the evidence needed to support her allegations. ECF No. 22. Although I was not persuaded by Respondent's arguments regarding onset (*id.* at 3), I determined that Petitioner had failed to provide sufficient evidence to satisfy the other requirements for a Table SIRVA claim, due to the location of her pain and the existence of potential alternative causes, or to support a non-Table version of the claim. *Id.* at 5.

In response, Petitioner filed additional evidence addressing primarily the onset issue which Respondent raised – a supplemental affidavit; documentation showing

Petitioner procured medical insurance providing coverage from September 6, 2018, to March 17, 2019; a patient history and occupational health assessment from late June 2018; a written response; and a status report indicating the case did not involve a workers' compensation claim. Exhibits 15-17, ECF Nos. 24-25; Petitioner's Brief in Response to Order to Show Cause ("Response"), ECF No. 26; Status Report, ECF No. 27. In the written response, she dedicated a large portion of her argument to the issue of onset. Response at 8-11.

When discussing the other deficiencies I noted, Petitioner failed to acknowledge the differences between the symptoms Petitioner reported in late 2017 and early 2018 and those she complained of in December 2018. Response at 11-16. She simultaneously emphasized the lack of evidence for a neurologic injury while relying on her earlier statement of radiating pain which she attributed to the vaccine hitting a nerve. *Id.* at 11-14. To support her claim of a logical cause and effect between vaccination and pain, she relied upon the timing of her initial symptoms and what she characterized as a lack of an alternative cause. *Id.* at 14-15.

Following a May 3, 2022 telephonic status conference, I instructed Petitioner to consider whether she wished to proceed based upon only the neurologic injury she described immediately post-vaccination through June 2018, or to provide further evidence linking the more traditional SIRVA symptoms she later reported in association with this earlier injury. Order, issued May 10, 2022, at 2, ECF No. 28. I cautioned that any physician statements regarding causation should clearly indicate that the treating physician has reviewed all relevant medical records before reaching any conclusion. *Id.* In response, Petitioner filed a status report indicating she "is unable to obtain any additional evidence as described in the Scheduling Order of May 10, 2022." ECF No. 29.

The matter is now ripe for adjudication.

II. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). According to the most recent version of the Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The specific criteria establishing a SIRVA are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (additional requirements set forth in the *Qualifications and Aids to Interpretations* ("QAI")). If a petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish

an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec'y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

III. Analysis

To support his assertion that Petitioner has failed to establish that the onset of her pain occurred within 48 hours of vaccination, Respondent emphasizes the more than six-month delay between Petitioner's vaccination and the date she first sought medical treatment, plus information contained in a Facebook message Petitioner sent to her trainer. Rule 4(c) Report at 2. Stressing that Petitioner received immunizations and TB

tests on numerous occasions prior to vaccination, he characterizes Petitioner's rationale for the delay in treatment - that she was uninsured at the time - as not credible. *Id.*

However, and as I previously stated, I do not find Respondent's onset objections to be persuasive. The cost of an immunization or TB test, often required for employment, is undoubtedly less than a visit for an illness or injury – and hence it is not unreasonable for a petitioner to avoid the greater cost of an actual doctor's visit. Additionally, in the same October 19, 2017 Facebook message at issue (containing the description of three days of pain upon which Respondent relies), Petitioner clearly attributes her injury to the flu vaccine she received. Exhibit 10 at 1. And if Petitioner is counting the date of vaccination/onset as well as the date of the message, her description of a three-day duration for her pain is accurate.

But deciding the above issue in Petitioner's favor does not resolve the present dispute. More problematic are the issues related to the nature and cause of Petitioner's reported symptoms. When Petitioner first complained of left shoulder pain, she described symptoms *above* her shoulder and radiating to her fingers – all of which appear more neurological in nature. Thus, in the Facebook message to her trainer, Petitioner described a stiff neck along with an inability to turn her head, headache, and knot in her arm. Exhibit 10 at 1. Later that day, she indicated that she had "a little more range of motion in [her] neck tonight," adding that her "instructor[ ] said today that they possibly hit a nerve." *Id.* at 2. Five days later, she reported that she had her injury "checked out and [her] C5 nerve was hit by the needle…she gave me the shot too low below the deltoid." *Id.* at 3. She described her pain as "radiat[ing] clear up [her] neck n [sic] into [her] head …causing migraine-like pain." *Id.* at 4. Petitioner further reported that her mother previously had the same type of injury which improved after physical therapy ("PT"). *Id.* at 3. In a status report, filed on March 2, 2021, Petitioner indicated that her sister, a registered nurse, was the individual who examined her during his time. ECF No. 18.

Petitioner did not otherwise seek treatment until late April 2018, when she was seen at the Knox Country Community Health Center, complaining of "numbness, tingling, and pain in the left shoulder radiating down into her fingers since having a flu shot last October." Exhibit 13 at 13. Her prior history of trigeminal neuralgia is noted in the record from this visit. *Id.*; *see also* Exhibit 3 at 8-12 (regarding a 2015-16 complaint of right-sided facial pain and left-sided Bells Palsy seven to eight years earlier). It appears she continues to take Gabapentin for this prior pain. Exhibit 11 at 6, 9-10.

On May 11, 2018, Petitioner visited the neurologist who had treated her 2015-16 facial pain, complaining of left shoulder pain which radiated into her hand. Exhibit 3 at 21-23. She reported that pain which had radiated into her neck had resolved. *Id.* at 21. An EMG was ordered. *Id.* at 23. Performed on June 11, 2018, the EMG revealed no evidence

of "cervical radiculopathy, brachial plexopathy, or ulnar neuropathy" and only incidental electrodiagnostic evidence of "left median nerve entrapment at the wrist." *Id.* at 24.

As I previously indicated in my January 18, 2022 Order to Show Cause, nerve-related injuries such as that Petitioner initially described have been compensated in the Vaccine Program, although as causation-in-fact claims, rather than Table SIRVA claims. *See, e.g., Kirby v. Sec'y of Health & Hum. Servs.*, No. 16-0185V, 2019 WL 6336026 (Fed. Cl. Spec. Mstr. May 27, 2020), *review granted, decision rev'd on other grounds*, 148 Fed. Cl. 530 (2020), *reinstated* 997 F.3d 1378 (Fed. Cir. 2021). However, in this case there is significant evidence which undercuts a non-Table claim. By May 11th, Petitioner's upwardly radiating pain had resolved, and she reported only pain traveling into her left hand. The subsequent June 2018 EMG revealed only incidental findings related to Petitioner's left wrist, and otherwise normal results. And Petitioner has a history of facial pain, for which she was still taking Gabapentin.

Following the June 11, 2018 EMG, Petitioner did not seek medical treatment for left shoulder pain until December 2018. Exhibit 4 at 5-7. During that six-month period, she was seen for a lower back injury sustained while lifting a patient in October 2018[3] – attending four PT sessions to treat this pain, and an upper respiratory illness in November. Exhibit 11 at 6-14; Exhibit 12 at 4-15. There is no mention of left shoulder pain in the records from these visits. *Id.* And in her PT records, it is specifically noted that Petitioner had pain *only* in her lower left back. Exhibit 12 at 6, 10-11, 13-14.

On December 17, 2018, Petitioner was seen by an orthopedist, complaining of left shoulder soreness and decreased ROM which she attributed to the flu vaccine she received fourteen months earlier. Exhibit 4 at 5. She described her pain as a dull ache - located over the lateral aspect of her left arm and aggravated by physical activity. *Id.* Although these symptoms are typical of those usually reported following a SIRVA injury, Petitioner did not provide this account until more than a year post-vaccination. Additionally, she reported that she had undergone PT which failed to alleviate her pain – an allegation not supported by the record in this case.

Additionally, x-rays, performed that day, showed mild ossification, calcification, and moderate osteoarthritis. Exhibit 4 at 14. An MRI, performed on January 11, 2019, showed the same ossification, a globular calcium deposit in the distal supraspinatus tendon consistent with moderate calcific tendinitis, no rotator cuff tear or edema, and mild joint osteoarthritis and subacromial/subdeltoid bursitis. *Id*. at 13. Petitioner attended four

[3] Petitioner described having her right arm under the patient's armpit while attempting a two-person lift, trying to avoid spilling hot liquid (soup) on the patient's chest. Exhibit 11 at 9.

acupuncture sessions in February and March 2019. Exhibit 5 at 2-4. Other than a TB test from April 2019 (Exhibit 11 at 4-5), no further medical records have been filed.

When filing her petition, Petitioner provided affidavits from her parents and sister. Exhibits 7-9. Although these affidavits provide further support for Petitioner's onset claims, they do not address the more problematic deficiencies in Petitioner's case discussed above.

Petitioner has provided two differing accounts of left shoulder pain. Her initial pain appeared to be neurologic, centered in her neck and accompanied by a severe headache. However, based upon the record as it currently stands, there is insufficient evidence of causation for this earlier neurologic injury which confers the timing needed to establish an appropriate onset. And, considering that the upwardly radiating pain Petitioner initially reported did not appear to be present in late April 2018, and was reported to be resolved by May 11th, the record as it currently stands does not support a finding of six months of sequelae based upon only this earlier described injury.

After testing revealed a lack of support for a neurological condition, Petitioner did not seek additional treatment for this radiating pain. When seen by an orthopedist six months later, following a period when she sought medical treatment for other conditions and failed to report any left shoulder pain, Petitioner reported a *different* type of pain - a dull ache over her later shoulder. She had not previously reported these symptoms. And testing revealed other potential causes of this new pain, such as moderate calcific tendinosis and mild joint osteoarthritis. Unless these later symptoms can be linked to the injury Petitioner initially described, it is unlikely that Petitioner could establish the appropriate required causal link and timing for a vaccine-related injury.

It was conceivable that these claim inconsistencies could be resolved with evidence – whether provided by an expert, medical literature, or the record itself. Petitioner was provided with the opportunity to provide additional evidence and argument regarding this shortcoming - but declined to do so. She also failed to indicate whether she wished to continue based solely upon her earlier injury or wished to provide further evidence to link the differing symptoms. Accordingly, I cannot find on the record as it stands that *either* a Table SIRVA claim, or non-Table claim for some other distinguishable form of neuropathic injury, could be sustained.

IV. Conclusion

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support her allegation of a left shoulder injury caused by the flu vaccine she received on October 11, 2017. Petitioner was informed that failure to provide

preponderant to support her claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for the claim. Accordingly, this case is DISMISSED for failure to prosecute and insufficient evidence. The Clerk of Court shall enter judgment accordingly.[4]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[4] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.